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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/044,006 01/11/2002 Alexander Baguisi 21578-007 8234 7590 08/13/2003 **EXAMINER** MINTZ, LEVIN, COHEN, FERRIS, WILSON, MICHAEL C GLOVSKY and POPEO, P.C. ART UNIT PAPER NUMBER One Financial Center Boston, MA 02111 1632

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No		Applicant(s)	
		10/044,006		BAGUISI ET AL.	
Office Action Summary		Examiner		Art Unit	
		Michael C. Wilso	in .	1632	
Period fo	The MAILING DATE of this communication or Reply	appears on the cove	r sheet with the c	orrespondence address	
THE N - Exter after - If the - If NO - Failur - Any re	DRTENED STATUTORY PERIOD FOR REIMAILING DATE OF THIS COMMUNICATION IS COMMUNICATION IN COMMUNICATION IS COMMUNICATION IN COMM	N. R. 1.136(a). In no event, how reply within the statutory mi iod will apply and will expire atute, cause the application to	ever, may a reply be tim nimum of thirty (30) days SIX (6) MONTHS from to become ABANDONED	ely filed will be considered timely. he mailing date of this communication. 0 (35 U.S.C. § 133).	
1) 🗌	Responsive to communication(s) filed on _	<u></u> -			
2a) <u></u> □	This action is FINAL. 2b)	This action is non-f	nal.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims					
4) 🖾	Claim(s) 1-25 is/are pending in the applicat	tion.			
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6)⊠	6)⊠ Claim(s) <u>1-25</u> is/are rejected.				
7)	Claim(s) is/are objected to.				
	Claim(s) are subject to restriction and on Papers	d/or election require	ment.		
9) 🗌 🗆	The specification is objected to by the Exami	iner.			
10) 🔲 🗆	The drawing(s) filed on is/are: a)□ ac	cepted or b) object	ed to by the Exan	niner.	
	Applicant may not request that any objection to		-		
11) 🔲 🗆	The proposed drawing correction filed on	is: a)⊡ approv	ed b)∏ disappro	ved by the Examiner.	
	If approved, corrected drawings are required in	reply to this Office ac	tion.		
12) 🔲 🗆	The oath or declaration is objected to by the	Examiner.			
Priority u	nder 35 U.S.C. §§ 119 and 120				
13)	Acknowledgment is made of a claim for fore	eign priority under 3	5 U.S.C. § 119(a)	-(d) or (f).	
a) ☐ All b) ☐ Some * c) ☐ None of:					
	1. Certified copies of the priority docume	ents have been rece	eived.		
	2. Certified copies of the priority documents have been received in Application No				
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
	cknowledgment is made of a claim for dome		•		
	☐ The translation of the foreign language			• • • • • • • • • • • • • • • • • • • •	
	cknowledgment is made of a claim for dome				
Attachment		- -	•		
2) 🔲 Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s	4)		(PTO-413) Paper No(s) atent Application (PTO-152)	
	ademark Office				

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-5 and 25, drawn to an avian gonad cell comprising a heterologous nucleic acid, classified in class 435, subclass 325.
- II. Claims 6-22, drawn to a method of introducing a nucleic acid sequence into the genome of an avian comprising contacting gonad cells isolated from a chick embryo with a nucleic acid molecule and transferring the cells to a fertilized recipient embryo, classified in class 800, subclass 21.
- III. Claim 23, drawn to a gonad cell having a disruption of an endogenous gene that inhibits the production of functional gene product, classified in class 435, subclass 325.
- IV. Claim 24, drawn to an avian egg having a xenogeneic PGC, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are patentably distinct because the cells of Group I have a different scope than those required for Group II. In addition, the cells of group I do not have to be used to introduce a nucleic acid into the genome of an avian as in Group II. For example, the cells of Group I may be a PGC cell line expressing a growth factor.

Groups I and III are patentably distinct because the cells of Group I express heterologous proteins while the cells of Group III do not. The cells of Group III have a

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disruption in an endogenous gene while the cells of Group I do not. The cells of Group I have a heterologous nucleic acid while the disruption of a gene in the cells of Group III may occur naturally.

Group I and IV are patentably distinct because the cells of Group I may be used to make an avian expressing a heterologous protein while the egg of Group IV may be used to make an avian of two different species. The egg of Group IV does not require a heterologous nucleic acid as in Group I. The cells of Group I do not have to be used in a xenogeneic species as in Group IV.

Groups II and III are patentably distinct because the method of Group II is used to make transgenic avians while the cells of Group III may be used to create a PGC cell line that does not produce a protein. The cells of Group III have a disruption in an endogenous gene while the cells used in the method of Group II do not. The cells used in the method of Group II have a nucleic acid while the disruption of a gene in the cells of Group III may occur naturally.

Group II and IV are patentably distinct because the cells used in the method of Group II may be used to make an avian expressing a heterologous protein while the egg of Group IV may be used to make an avian of two different species. The egg of Group IV does not require a nucleic acid as in Group II. The cells used in the method of Group II do not have to be used in a xenogeneic species as in Group IV.

Group III and IV are patentably distinct because the cells of Group III may be used to make an avian that does not produce a particular protein (knockout avian) while the egg of Group IV may be used to make an avian of two different species. The egg of

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Group IV does not require a disruption in a gene as in the cells of Group III. The cells of

Group III do not have to be used in a xenogeneic species as in Group IV.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL WILSON PRIMARY EXAMINER